

### REMARKS

Claims 53-58 are currently pending in this application. Claims 53, 54 and 57 have been amended. No new matter has been added. In view of these amendments and of the following remarks, Applicants believe that all the asserted rejections are in condition for withdrawal and all the claims are in condition for allowance.

The Examiner states that the descriptions of the Figures are located at various places throughout the specification. The specification has been amended to conform to 37 C.F.R. 1.77(b).

The claims are objected to because claim 53 refers to Figure 4A rather than a SEQ ID NO. Claim 53 has been amended to recite "SEQ ID NO. 116," thus mooting this objection.

Claims 53-58 stand rejected under 35 U.S.C. 112, second paragraph, for purported indefiniteness. The Examiner asserts that it is not clear whether the recitation of claim 53 refers only to the length of the claimed sequence or to a specific sequence. The Examiner further asserts that claims 54-57 are indefinite because it is not clear what nucleic acid sequences are encompassed by "a nucleic acid sequence derived from a translocation partner of PLAG1," and the specification does not define this recitation. Additionally, the Examiner asserts that claim 58 is indefinite over "an antisense nucleic acid sequence of the nucleic acid sequence according to claim 53."

Claim 53 has been amended to recite the specific nucleic acid sequence, and thus does not merely refer to the length of the claimed sequence. Claim 54 has been amended to recite that the fragment of the nucleic acid sequence according to claim 53 is fused to a nucleic acid sequence comprised of a translocation partner of PLAG1. With respect to the Examiner's assertion that the specification does not define this recitation, Applicants direct the Examiner to page 2, line 37 continuing to page 3, line 5, in which it is stated that the CTNNB1 gene was identified as the fusion, i.e., translocation, partner gene of PLAG1. With respect to the Examiner's assertion of indefiniteness of claim 58, Applicants respectfully submit that one skilled in the art would recognize that an anti-sense nucleic acid sequence of a particular nucleic acid sequence, such as the nucleic acid sequence recited in claim 58, is a sequence which is

complementary to the particular nucleic acid. Clarification of the types of anti-sense nucleic acids encompassed by claim 58 can be found on page 10, lines 25-26.

Claims 54-58 stand rejected under 35 U.S.C. 112, first paragraph, for purported lack of written description. The Examiner asserts that the specification only provides support for the fusion partner consisting of CTNNB1, and thus claim 54 is considered to encompass new matter. The Examiner further asserts that there is no support for the recitation "614 base pairs," and thus claim 57 constitutes new matter. Additionally, the Examiner asserts that claim 58 constitutes new matter because the recitation of "or fragments thereof" or "tumor cells" is not supported in the specification.

As stated above, claim 54 has been amended to recite a fragment of the nucleic acid sequence according to claim 53 fused to a nucleic acid sequence comprised of a translocation partner of PLAG1, which support can be found on page 2, lines 37-38 and page 10, line 29. Claim 57 has been amended to delete "615" base pairs and to now recite "605" base pairs. In claim 58, support for "or fragments thereof" is found on page 10, line 27, and support for "tumor cells" is found on page 10, line 10.

Claims 54, 55 and 58 stand rejected under 35 U.S.C. 112, first paragraph, for purported lack of written description, and claims 54-58 stand rejected under 35 U.S.C. 112, first paragraph, for purported lack of enablement. The Examiner asserts that the specification does not teach or enable isolated hybrid nucleic acids consisting of any fragment of the nucleic acid sequence according to claim 53 fused to any nucleic acid sequence "derived from a translocation partner of PLAG1."

As the Examiner correctly states, the specification states that CTNNB1 is a translocation partner of PLAG1. The specification also provides a hybrid nucleic acid sequence consisting of exon 1 of CTNNB1 fused to exons 3 to 5 of PLAG1, and exon 1 of CTNNB1 fused to exons 2 to 5 of PLAG1. Furthermore, specific fragments of PLAG1 are disclosed which are fused to other nucleic acids. Applicants point out that the PLAG1 protein is structurally defined in detail in the specification, so that designing fragments of PLAG1 would be obvious to those skilled in the art without undue experimentation. Also known by those skilled in the art is how to design anti-sense nucleic acids against a particular nucleic acid, such as PLAG1. Thus,

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Applicants submit that the specification provides more than adequate written description and enablement for those skilled in the art to design an isolated hybrid nucleic acid consisting of a fragment of the nucleic acid sequence according to claim 53 fused to a nucleic acid sequence comprised of a translocation partner of PLAG1, which will inhibit expression of the nucleic acid sequence according to claim 53 in a tumor cell.

Claims 54-55 stand rejected under 35 U.S.C. 102(b) for purported anticipation by Nollet et al. The Examiner asserts that Nollet et al. anticipates the claimed invention of an isolated hybrid consisting of a fragment of the nucleic acid sequence according to claim 53 fused to a nucleic acid sequence derived from a CTNNB1 translocation partner, wherein the presence of the hybrid allows the diagnosis of a cell containing the hybrid nucleic acid sequence as a tumor cell. The Examiner directs Applicants' attention to pages 414-415 and 420-421 of the Nollet et al reference.


Nollet et al. teach that the cytoplasmic  $\beta$ -catenin protein is implicated in signal transduction and associates with both the cell-cell adhesion protein E-cadherin and the tumor suppressor gene product APC. Nollet et al. also teach the primary structure of CTNNB1 (the  $\beta$ -catenin gene) by analyzing cDNA and genomic clones. Nowhere in the Nollet et al. reference is a hybrid nucleic acid sequence taught or suggested consisting of a fragment of a PLAG1 nucleic acid sequence according to claim 53 fused to a nucleic acid sequence derived from a CTNNB1 translocation partner, wherein the presence of the hybrid allows the diagnosis of a cell containing the hybrid nucleic acid sequence as a tumor cell. Indeed, nowhere in Nollet et al. is a PLAG1 nucleic acid sequence taught or suggested. Thus, Nollet et al. does not anticipate or even suggest Applicants' invention as now claimed.

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For all the foregoing reasons, claims 53-58 are patentable over the cited prior art and in condition for allowance. Withdrawal of the asserted rejections and allowance of all pending claims 53-58 is respectfully requested.

Respectfully submitted,

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